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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,351	06/07/2002	Stace Lindsay	06727/008002	8638

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EXAMINER

BERTOGLIO, VALARIE E

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 08/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/030,351

Applicant(s)

LINDSAY ET AL.

Examiner

Valarie Bertoglio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, drawn to a nucleic acid encoding rHuAFP operably linked to a milk specific promoter.

Group II, claim(s) 2, drawn to a nucleic acid encoding rHuAFP operably linked to a urine specific promoter.

Group III, claim(s) 3,5-7,10,11, drawn to a non-human transgenic mammal comprising and expressing said nucleic acid, milk isolated from said mammal and a method of producing milk using the mammal.

Group IV, claim(s) 4,5,8,9,12,13, drawn to a non-human transgenic mammal comprising and expressing said nucleic acid, urine isolated from said mammal and a method of producing milk using the mammal.

Group V, claim(s) 14,15,18-20, drawn to a method of treating a patient using milk comprising rHuAFP.

Group VI, claim(s) 16-20, drawn to a method of treating a patient using rHuAFP.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I and II are distinct nucleic acids comprising different promoters rendering the nucleic acids structurally and functionally distinct. The nucleic acids have different activities in

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different cell types. The nucleic acid of Group I can be used to express rHuAFP in milk-producing cells. The nucleic acid of Group II can be used to express rHuAFP in urine-producing cells. The nucleic acid of each invention is not necessary for making or using the other.

The nucleic acid of Group I and the non-human transgenic mammal of Group III are distinct because the nucleic acid has multiple uses that differ from that of III. The nucleic acid of Group I can be used to express rHuAFP in cells in vitro, which does not require the mammal or methods of producing milk or the milk of Group III.

The nucleic acid of Group I and the non-human transgenic mammal of Group III are distinct because the nucleic acid has multiple uses that differ from that of III. The nucleic acid of Group I can be used to express rHuAFP in mammary cells in vitro, which does not require the mammal or methods of using a mammal or the urine of Group III.

The nucleic acid of Group II and the non-human transgenic mammal of Group III are distinct because the nucleic acid has multiple uses that differ from that of III. The nucleic acid of Group II can be used to express rHuAFP in cells in vitro, which does not require the mammal or methods of producing urine or the urine of Group III.

The nucleic acid of Group II and the non-human transgenic mammal of Group IV are distinct because the nucleic acid has multiple uses that differ from that of IV. The nucleic acid of Group II can be used to express rHuAFP in cells in vitro, which does not require the mammal or methods of using the mammal or the urine of Group IV.

The nucleic acids of Groups I and II are distinct from the methods of Groups V and VI because the nucleic acids are not necessary for the methods and the methods are not necessary for the nucleic acids. Groups I and II are drawn to nucleic acids that can be used to express

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rHuAFP using recombinant DNA technology. The methods of Groups V and VI are methods of treating a patient that do not require the nucleic acids.

The mammals of Groups III and IV are distinct from the methods of Groups V and VI because the mammals are not necessary for the methods and the methods are not necessary for the mammals. Groups III and IV are drawn to mammals that can be used to express rHuAFP in milk or urine using recombinant DNA technology. The methods of Groups V and VI are methods of treating a patient that do not require the mammals.

The methods of Groups V and VI are distinct because they require different method steps and different technical considerations. Group V is drawn to a method of treatment by administering milk. Group VI is drawn to a method of treatment by administering rHuAFP as a purified protein. Neither method is required one for the other.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Valarie Bertoglio  
Examiner  
Art Unit 1632

*Joe Waitad*  
AU1632